

REMARKS

In response to the Requirement for Restriction of September 25, 2009, Applicants hereby elect, with traverse, to prosecute the claims in Group I, namely claims 24-33 and 37 which are drawn to a process of making a plasticized PLGA.

The traverse is based on the grounds that the objection based on a lack of a single general inventive concept is groundless.

In point of fact, the Examiner's reasoning is premised upon an assumption, namely, that Claims 24-33 are drawn to a process for making plasticized PLGA. That, however, is not the case. Indeed, these claims are "product-by-process claims", within the meaning provided in MPEP 2113, i.e., claims, wherein a product is claimed, being defined by the process of its manufacture.

Insofar as claims 34-36 are concerned, the subcutaneous implants are products comprising the plasticized PLGA according to claim 24 and active principles. Therefore, the implants as claimed include all of the features of independent claim 24.

Furthermore, claims 37-40 define a process for making the above subcutaneous implants, having both the plasticized PLGA according to claim 24 and active principles as starting materials.

In claim 24, a step h) has been added, namely:

h) optionally mixing active ingredients with PLGA plasticized with ethanol obtained by step g).

Support can be found at page 2, line 32 and page 4, line 1.

Amended claim 24 contains the optional step h), specifying the mixing of the active agents with the plasticized PLGA. In this way, Group I relating to the product-by-process PLGA, also contains a reference to the active agents, which are present in claims 36 and 37.

The plasticized PLGA itself is the **special technical feature** corresponding to the **single general inventive concept** of the current application.

This also means that PCT Rule 13.1, as mentioned by the Examiner, concerning the requirement of “unity of invention,” is met.

Particularly, PCT Rule 13.2 recites:

“...the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.”

The Examiner states that PCT Rule 13.2 is not fulfilled because Group II claims bioactive agents which are not present in plasticized PLGA of Group I.

As clarified above, this derives from a misinterpretation of the claimed subject-matter. Actually, the plasticized PLGA in claims 24-33 is a product, and subcutaneous implants comprise said product and active principles.

In view of the above, Applicants respectfully urge that the technical features of the plasticized PLGA according to claim 24 are **special features** that correspond to a **single general inventive concept**. In this regard, Applicants respectfully submit that there is no basis for a lack of unity objection and therefore it is unjustified to maintain it.

Since claims 34-36, which are directed to non-elected Group II, include all of the limitations of the allowable product claims 24-33 and 37-40, claims 34-36 should be considered for rejoinder.

CONCLUSION

In view of the foregoing, Applicants believe that the currently pending Application meets the requirements of unity of invention on the ground that the

arguments provided fully overcome the objections raised in the outstanding Office Action.

Please charge any fees which may be due and which have not been submitted herewith to our Deposit Account No. 01-0035.

Respectfully submitted,

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